DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 17 2012

Re: FERAHEME
Docket No.: FDA-2010-E-0049

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,599,498, filed by AMAG Pharmaceuticals, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for FERAHEME (ferumoxytol), the human drug product claimed by the patent.

The total length of the regulatory review period for FERAHEME (ferumoxytol) is 3,680 days. Of this time, 3,120 days occurred during the testing phase and 560 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 5, 1999.

   The applicant claims June 4, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 5, 1999, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 19, 2007.

   The applicant claims December 18, 2007, as the date the new drug application (NDA) for FERAHEME (NDA 22-180) was initially submitted. However, FDA records indicate that NDA 22-180 was submitted on December 19, 2007

3. The date the application was approved: June 30, 2009.

   FDA has verified the applicant's claim that NDA 22-180 was approved on June 30, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Bruce D. Sunstein
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